

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing:

10 September 1999 (10.09.99)

International application No.:

PCT/AU99/00136

Applicant's or agent's file reference:

91570

International filing date:

05 March 1999 (05.03.99)

Priority date:

06 March 1998 (06.03.98)

Applicant:

COIA, Gregory et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International preliminary Examining Authority on:

09 July 1999 (09.07.99)



in a notice effecting later election filed with the International Bureau on:

2. The election



was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer:

J. Zahra

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br>91570          | <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"><b>FOR FURTHER ACTION</b></div> <div>see Notification of Transmittal of International Search Report<br/>(Form PCT/ISA/220) as well as, where applicable, item 5 below.</div> </div> |   |
| International application No.<br><b>PCT/AU 99/00136</b> | International filing date ( <i>day/month/year</i> )<br><b>5 March 1999</b>  | (Earliest) Priority Date ( <i>day/month/year</i> )<br><b>6 March 1998</b> |

Applicant  
**DIATECH PTY LTD**

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of ~~3~~<sup>4</sup> sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract, ☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ None of the figures

☐ because the applicant failed to suggest a figure

☐ because this figure better characterizes the invention

☐

|  |  |  |  |   |   |  |   |  |  |   |  |  |
|--|--|--|--|---|---|--|---|--|--|---|--|--|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>   |  |  |  |   |   |  |   |  |  |   |  |  |
| Int Cl <sup>6</sup> : C12N 15/12, 15/13; C07K 14/705, 14/73, 14/665, 14/745<br>A61K 38/31, 38/04; 39/395<br>According to International Patent Classification (IPC) or to both national classification and IPC  |  |  |  |   |   |  |   |  |  |   |  |  |
| <b>B. FIELDS SEARCHED</b>  |  |  |  |   |   |  |   |  |  |   |  |  |
| Minimum documentation searched (classification system followed by classification symbols)<br>As above  |  |  |  |   |   |  |   |  |  |   |  |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>As below  |  |  |  |   |   |  |   |  |  |   |  |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br><u>Medline &amp; CA</u> : Receptors, antigen: CTLA.4, CD28, ICOS, <u>WPAT</u> :- variable region or domain, CDR, variable and region or domain, CDR, soluble/solubility, CTLA-4, CD28, ICOS  |  |  |  |   |   |  |   |  |  |   |  |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |  |  |  |   |   |  |   |  |  |   |  |  |
| Category*  | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.  |  |   |   |  |   |  |  |   |  |  |
| X  | Jung S and Pluckthun A. Protein Eng. 1997. 10(8): 959-966  | 1-10, 13   |  |   |   |  |   |  |  |   |  |  |
| Y  | Patten et al. J Immunol. 1993. 150(6): 2281-2294   | All  |  |   |   |  |   |  |  |   |  |  |
| Y  | WO 91/10438 (Protein Design Labs Inc) 1991   | All  |  |   |   |  |   |  |  |   |  |  |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex  |  |  |  |   |   |  |   |  |  |   |  |  |
| <p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table> |  |  | "A" document defining the general state of the art which is not considered to be of particular relevance | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | "E" earlier application or patent but published on or after the international filing date | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | "O" document referring to an oral disclosure, use, exhibition or other means | "&" document member of the same patent family | "P" document published prior to the international filing date but later than the priority date claimed |  |
| "A" document defining the general state of the art which is not considered to be of particular relevance   | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |  |  |   |   |  |   |  |  |   |  |  |
| "E" earlier application or patent but published on or after the international filing date  | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |  |  |   |   |  |   |  |  |   |  |  |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |  |  |   |   |  |   |  |  |   |  |  |
| "O" document referring to an oral disclosure, use, exhibition or other means   | "&" document member of the same patent family  |  |  |   |   |  |   |  |  |   |  |  |
| "P" document published prior to the international filing date but later than the priority date claimed   |  |  |  |   |   |  |   |  |  |   |  |  |
| Date of the actual completion of the international search<br>30 March 1999   |  | Date of mailing of the international search report<br>13 APR 1999        |  |   |   |  |   |  |  |   |  |  |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200<br>WODEN ACT 2606<br>AUSTRALIA<br>Facsimile No.: (02) 6285 3929   |  | Authorized officer<br><br>GILLIAN ALLEN<br>Telephone No.: (02) 6283 2266 |  |   |   |  |   |  |  |   |  |  |

**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages              | Relevant to claim No. |
|-----------|---|-----------------------|
| Y         | Peach RJ et al. J Exp Med. 1994. 180(6): 2049-2058  | All                   |
| Y         | Davies J and Reichman L. Protein Eng. 1996. 9(6): 531-537. Medline Abstract. Cited by applicant | 16-17                 |

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

International application No.  
PCT/AU 99/00136

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report |         | Patent Family Member |          |
|--|---------|----------------------|----------|
| WO                                     | 9110438 | AU                   | 71825/91 |
|  |         | US                   | 5216132  |
| END OF ANNEX                           |         |                      |          |

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>91570   | <b>FOR FURTHER ACTION</b>   | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International application No.<br>PCT/AU 99/00136   | International filing date ( <i>day/month/year</i> )<br>5 March 1999 | Priority Date ( <i>day/month/year</i> )<br>6 March 1998  |
| International Patent Classification (IPC) or national classification and IPC<br><br>Int. Cl. <sup>6</sup> C12N 15/12, 15/13; C07K 14/705, 14/73, 14/665, 14/745; A61K 38/04, 38/31, 39/395 |   |  |
| Applicant<br>Diatech Pty Ltd   |   |  |

|  |   |   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
|--|---|---|-------------------------------------|---------------------|----|--------------------------|----------|-----|--------------------------|--|----|--------------------------|----------------------------|---|-------------------------------------|---|----|--------------------------|-------------------------|-----|--------------------------|--|------|--------------------------|---|
| 1.   | This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.  |   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| 2.   | This REPORT consists of a total of <b>4</b> sheets, including this cover sheet.<br><br><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).<br><br>These annexes consist of a total of      sheet(s). |   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| 3. This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%; text-align: center;"><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table> |   | I   | <input checked="" type="checkbox"/> | Basis of the report | II | <input type="checkbox"/> | Priority | III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | IV | <input type="checkbox"/> | Lack of unity of invention | V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | VI | <input type="checkbox"/> | Certain documents cited | VII | <input type="checkbox"/> | Certain defects in the international application | VIII | <input type="checkbox"/> | Certain observations on the international application |
| I  | <input checked="" type="checkbox"/>   | Basis of the report   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| II   | <input type="checkbox"/>  | Priority  |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| III  | <input type="checkbox"/>  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| IV   | <input type="checkbox"/>  | Lack of unity of invention  |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| V  | <input checked="" type="checkbox"/>   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| VI   | <input type="checkbox"/>  | Certain documents cited   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| VII  | <input type="checkbox"/>  | Certain defects in the international application  |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |
| VIII   | <input type="checkbox"/>  | Certain observations on the international application   |                                     |                     |    |                          |          |     |                          |  |    |                          |                            |   |                                     |   |    |                          |                         |     |                          |  |      |                          |   |

|  |   |
|--|---|
| Date of submission of the demand<br>15 July 1999   | Date of completion of the report<br>15/10/99                            |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200<br>WODEN ACT 2606<br>AUSTRALIA<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br>Gillian Allen<br>Telephone No. (02) 6283 2266 |

**L Basis of the report**

1. With regard to the elements of the international application:\*
- ☒ the international application as originally filed.
- ☐ the description,      pages , as originally filed,  
   pages , filed with the demand,  
   pages , filed with the letter of .
- ☐ the claims,      pages , as originally filed,  
   pages , as amended (together with any statement) under Article 19,  
   pages , filed with the demand,  
   pages , filed with the letter of .
- ☐ the drawings,      pages , as originally filed,  
   pages , filed with the demand,  
   pages , filed with the letter of .
- ☐ the sequence listing part of the description:  
   pages , as originally filed  
   pages , filed with the demand  
   pages , filed with the letter of .
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:
- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description,      pages
- ☐ the claims,      Nos.
- ☐ the drawings,      sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |                    |     |
|-------------------------------|--------------------|-----|
| Novelty (N)                   | Claims 1-33        | YES |
|                               | Claims             | NO  |
| Inventive step (IS)           | Claims 1-33        | YES |
|                               | Claims             | NO  |
| Industrial applicability (IA) | Claims 1-28, 30-33 | YES |
|                               | Claims             | NO  |

**2. Citations and explanations (Rule 70.7)**Citations

- D1. Jung S and Pluckthorn A. Protein Eng. 1997. 10(8): 959-966.  
D2. Patten et al. J Immunol. 1993. 150(6): 2281-2294  
D3. WO 91/10438. (Protein Design Labs Inc.) 1991  
D4. Peach et al. J Exp Med. 1994. 180(6): 2049-2058.  
D5. Davies and Reichman. Protein Eng. 1996. 9(6): 531-537.

Novelty.

There is no disclosure in the prior art that replacement or modification of the CDR loops of antibody like molecules results in molecules with improved solubility. It is accepted that the specific modifications of claim 3 have been shown to be associated with increased solubility of the V-like domains. Therefore, all claims are novel.

Inventive Step.

It is admitted by the applicant that the V-like domains of the non-antibody ligands of the present invention bear a strong resemblance to the variable domains of both immunoglobulin antibodies and the T cell receptor. Therefore it is considered that one skilled in the art would consider techniques and changes that have been applied to Ig and/or TCR molecules as being well worth consideration as at least a starting point in the manipulation of the non-antibody ligands of the present application.

D1 teaches that it is possible to improve the solubility of improperly folded antibody Fv molecules, whilst retaining its specificity, by grafting the CDR loops to a humanised antibody framework. However, this does not directly bear on the solution found by the present applicant, which grafts foreign CDR loops onto the V-like domain of non-antibody molecules, changing the specificity and improving the solubility.

D2 discloses the transfer of CDR loops between different T cell receptors. This discloses change in specificity, but there is no disclosure that altered solubility was sought or observed.

D3 discloses that the CDR loops of CD28 and CTLA-4 determine the binding specificities of these molecules, and that alteration to these CDR loops changes binding specificity. However, there is no suggestion that grafting or changing the CDR loops has any effect on solubility.



**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of : Box V**

D2 and D3 provide guidance on construction of alternate forms of V-like domains. However, since neither addresses the problem of solubility, they are not considered to anticipate forms of the V-like domain which have improved solubility because they have modified or grafted CDR loops.

D4 discloses soluble T cell receptor peptides obtained by fusing the V $\beta$  variable domain, which comprises the CDR loops to a constant region of any immunoglobulin superfamily molecule, which would include the non-antibody ligands of the present invention. However, although this addresses the solubility problem, the citation does not teach or suggest direct modification of CDR loops

D5 discloses camelisation of the V<sub>H</sub> region, with the modification of the V<sub>H</sub> region providing an intradomain disulphide bond which improves folding stability. One skilled in the art would tend to associate improved folding stability with improved solubility. However, this citation is not specifically directed to improvements in solubility, nor to non-antibody ligands.

Therefore all claims are considered inventive over the prior art.

**Industrial Applicability.**

Claim 29 is to method of treatment of the human body. No unified criterion exists within the member countries of the PCT as to the industrial applicability of such claims. The remaining claims are industrially applicable.

## PCT REQUEST

91570

Original (for SUBMISSION) - printed on 05.03.1999 11:30:16 AM

|                |  |  |
|----------------|--|--|
| <b>0</b>       | <b>For receiving Office use only</b>   |  |
| <b>0-1</b>     | International Application No.  |  |
| <b>0-2</b>     | International Filing Date  |  |
| <b>0-3</b>     | Name of receiving Office and "PCT International Application"   |  |
| <b>0-4</b>     | <b>Form - PCT/RO/101 PCT Request Prepared using</b>  | <b>PCT-EASY Version 2.80<br/>(updated 01.01.1999)</b>    |
| <b>0-5</b>     | <b>Petition</b><br>The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty |  |
| <b>0-6</b>     | <b>Receiving Office (specified by the applicant)</b>   | <b>Australian Patent Office (RO/AU)</b>                  |
| <b>0-7</b>     | <b>Applicant's or agent's file reference</b>   | <b>91570</b>   |
| <b>I</b>       | <b>Title of invention</b>  | <b>V-LIKE DOMAIN BINDING MOLECULES</b>                   |
| <b>II</b>      | <b>Applicant</b>   |  |
| <b>II-1</b>    | This person is:  | applicant only   |
| <b>II-2</b>    | Applicant for  | all designated States                                    |
| <b>II-4</b>    | Name   | DIATECH PTY LTD  |
| <b>II-5</b>    | Address:   | GPO Box 2434<br>Brisbane, Queensland 4001<br>Australia   |
| <b>II-6</b>    | State of nationality   | AU   |
| <b>II-7</b>    | State of residence   | AU   |
| <b>II-8</b>    | Telephone No.  | -  |
| <b>II-9</b>    | Facsimile No.  | -  |
| <b>II-10</b>   | e-mail   | -  |
| <b>III-1</b>   | <b>Applicant and/or inventor</b>   |  |
| <b>III-1-1</b> | This person is:  | applicant and inventor                                   |
| <b>III-1-2</b> | Applicant for  | US only  |
| <b>III-1-4</b> | Name (LAST, First)   | COIA, Gregory  |
| <b>III-1-5</b> | Address:   | 73 Union Street<br>Brunswick, Victoria 3056<br>Australia |
| <b>III-1-6</b> | State of nationality   | AU   |
| <b>III-1-7</b> | State of residence   | AU   |

## PCT REQUEST

91570

Original (for SUBMISSION) - printed on 05.03.1999 11:30:16 AM

|         |                           |   |
|---------|---------------------------|---|
| III-2   | Applicant and/or inventor |   |
| III-2-1 | This person is:           | applicant and inventor  |
| III-2-2 | Applicant for             | US only   |
| III-2-4 | Name (LAST, First)        | GALANIS, Maria  |
| III-2-5 | Address:                  | 5 Rowitta Drive<br>Glen Waverley, Victoria 3150<br>Australia  |
| III-2-6 | State of nationality      | AU  |
| III-2-7 | State of residence        | AU  |
| III-3   | Applicant and/or inventor |   |
| III-3-1 | This person is:           | applicant and inventor  |
| III-3-2 | Applicant for             | US only   |
| III-3-4 | Name (LAST, First)        | HUDSON, Peter John  |
| III-3-5 | Address:                  | 36 Fuschia Street<br>Blackburn, Victoria 3130<br>Australia    |
| III-3-6 | State of nationality      | AU  |
| III-3-7 | State of residence        | AU  |
| III-4   | Applicant and/or inventor |   |
| III-4-1 | This person is:           | applicant and inventor  |
| III-4-2 | Applicant for             | US only   |
| III-4-4 | Name (LAST, First)        | IRVING, Robert Alexander                                      |
| III-4-5 | Address:                  | 11 Honeysuckle Avenue<br>Mulgrave, Victoria 3170<br>Australia |
| III-4-6 | State of nationality      | AU  |
| III-4-7 | State of residence        | AU  |
| III-5   | Applicant and/or inventor |   |
| III-5-1 | This person is:           | applicant and inventor  |
| III-5-2 | Applicant for             | US only   |
| III-5-4 | Name (LAST, First)        | NUTTALL, Stewart Douglas                                      |
| III-5-5 | Address:                  | 75 Ford Street<br>Ivanhoe, Victoria 3079<br>Australia         |
| III-5-6 | State of nationality      | AU  |
| III-5-7 | State of residence        | AU  |

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|        |  |  |
|--------|--|--|
| IV-1   | <b>Agent or common representative; or address for correspondence</b><br>The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: | agent  |
| IV-1-1 | Name   | F B RICE & CO  |
| IV-1-2 | Address:   | 605 Darling Street<br>Balmain, New South Wales 2041<br>Australia   |
| IV-1-3 | Telephone No.  | (612) 9810 7133  |
| IV-1-4 | Facsimile No.  | (612) 9810 8200  |
| IV-1-5 | e-mail   | partners@fbrice.com.au   |
| V      | <b>Designation of States</b>   |  |
| V-1    | Regional Patent<br>(other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)  | AP: GH GM KE LS MW SD SZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT<br>EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT<br>EP: AT BE CH&LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT<br>OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT |
| V-2    | National Patent<br>(other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)  | AL AM AT AU AZ BA BB BG BR BY CA CH&LI<br>CN CU CZ DE DK EE ES FI GB GD GE GH GM<br>HR HU ID IL IN IS JP KE KG KP KR KZ LC<br>LK LR LS LT LU LV MD MG MK MN MW MX NO<br>NZ PL PT RO RU SD SE SG SI SK SL TJ TM<br>TR TT UA UG US UZ VN YU ZW   |

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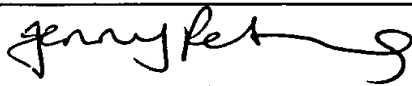
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|             |   |                            |
|-------------|---|----------------------------|
| <b>V-5</b>  | <b>Precautionary Designation Statement</b><br>In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. |                            |
| <b>V-6</b>  | <b>Exclusion(s) from precautionary designations</b>   | NONE                       |
| <b>VI-1</b> | <b>Priority claim of earlier national application</b>   |                            |
| VI-1-1      | Filing date   | 06 March 1998 (06.03.1998) |
| VI-1-2      | Number  | PP2210                     |
| VI-1-3      | Country   | AU                         |
| <b>VI-2</b> | <b>Priority document request</b><br>The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):   | VI-1                       |

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|         |  |  |                             |
|---------|--|--|-----------------------------|
| VII-1   | International Searching Authority Chosen                   | Australian Patent Office (ISA/AU)  |                             |
| VIII    | Check list   | number of sheets   | electronic file(s) attached |
| VIII-1  | Request  | 6  | -                           |
| VIII-2  | Description  | 91   | -                           |
| VIII-3  | Claims   | 4  | -                           |
| VIII-4  | Abstract   | 1  | 91570abs.txt                |
| VIII-5  | Drawings   | 15   | -                           |
| VIII-7  | TOTAL  | 117  |                             |
|         | Accompanying items   | paper document(s) attached   | electronic file(s) attached |
| VIII-8  | Fee calculation sheet                                      | ✓  | -                           |
| VIII-16 | PCT-EASY diskette  | -  | diskette                    |
| VIII-18 | Figure of the drawings which should accompany the abstract |  |                             |
| VIII-19 | Language of filing of the international application        | English  |                             |
| IX-1    | Signature of applicant or agent                            |  |                             |
| IX-1-1  | Name   | F B RICE & CO  |                             |
| IX-1-2  | Name of signatory  | Jenny Petering   |                             |

## FOR RECEIVING OFFICE USE ONLY

|      |   |  |
|------|---|--|
| 10-1 | Date of actual receipt of the purported international application |  |
|------|---|--|

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|        |   |        |
|--------|---|--------|
| 10-2   | Drawings:   |        |
| 10-2-1 | Received  |        |
| 10-2-2 | Not received  |        |
| 10-3   | Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application |        |
| 10-4   | Date of timely receipt of the required corrections under PCT Article 11(2)  |        |
| 10-5   | International Searching Authority   | ISA/AU |
| 10-6   | Transmittal of search copy delayed until search fee is paid   |        |

**FOR INTERNATIONAL BUREAU USE ONLY**

|      |  |  |
|------|--|--|
| 11-1 | Date of receipt of the record copy by the International Bureau |  |
|------|--|--|

**PCT (ANNEX - FEE CALCULATION SHEET)**

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(This sheet is not part of and does not count as a sheet of the international application)

|              |  |   |                     |
|--------------|--|---|---------------------|
| <b>0</b>     | <b>For receiving Office use only</b>   |   |                     |
| <b>0-1</b>   | International Application No.  |   |                     |
| <b>0-2</b>   | Date stamp of the receiving Office   |   |                     |
| <b>0-4</b>   | <b>Form - PCT/RO/101 (Annex)</b>   |   |                     |
| <b>0-4-1</b> | PCT Fee Calculation Sheet Prepared using   | PCT-EASY Version 2.80<br>(updated 01.01.1999) |                     |
| <b>0-9</b>   | Applicant's or agent's file reference  | 91570   |                     |
| <b>2</b>     | Applicant  | DIATECH PTY LTD, et al.                       |                     |
| <b>12</b>    | <b>Calculation of prescribed fees</b>  | fee amount/multiplier                         | total amounts (AUD) |
| <b>12-1</b>  | Transmittal fee T  | ⇒   | 100                 |
| <b>12-2</b>  | Search fee S   | ⇒   | 800                 |
| <b>12-3</b>  | International fee<br>Basic fee<br>(first 30 sheets) b1                               | 722   |                     |
| <b>12-4</b>  | Remaining sheets   | 87  |                     |
| <b>12-5</b>  | Additional amount (X)  | 17  |                     |
| <b>12-6</b>  | Total additional amount b2   | 1,479   |                     |
| <b>12-7</b>  | b1 + b2 = B  | 2,201   |                     |
| <b>12-8</b>  | Designation fees<br>Number of designations contained<br>in international application | 77  |                     |
| <b>12-9</b>  | Number of designation fees<br>payable (maximum 10)                                   | 10  |                     |
| <b>12-10</b> | Amount of designation fee (X)  | 166   |                     |
| <b>12-11</b> | Total designation fees D   | 1,660   |                     |
| <b>12-12</b> | PCT-EASY fee reduction R   | -222  |                     |
| <b>12-13</b> | Total International fee (B+D-R) I  | ⇒   | 3,639               |
| <b>12-14</b> | Fee for priority document<br>Number of priority documents<br>requested               | 1   |                     |
| <b>12-15</b> | Fee per document (X)   | 30  |                     |
| <b>12-16</b> | Total priority document fee P  | ⇒   | 30                  |
| <b>12-17</b> | <b>TOTAL FEES PAYABLE (T+S+I+P)</b>  | ⇒   | 4,569               |
| <b>12-19</b> | Mode of payment  | cheque  |                     |

**VALIDATION LOG AND REMARKS**

|               |                               |   |
|---------------|-------------------------------|---|
| <b>13-1-1</b> | Applicant remarks<br>Annotate | Sequence Listing pages have been included as part of the description for the fee calculation sheet. |
|---------------|-------------------------------|---|